PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Placke, Michael E., et. al.	Group No.: Unknown
Serial No.: Unknown	Examiner: Unknown
Filed: Herewith	
For: Formulation And Methods For Treating Neoplasms by Inhalation	

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PRELIMINARY AMENDMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

Prior to examination of the above-referenced application kindly amend the application as follows:

IN THE CLAIMS

Please cancel Claims 1 – 127 without prejudice to Applicants to prosecute such claims in related applications.

Please add the following new claims 128 -150.

128. A method of treating cancer of the respiratory tract in a patient in need of treatment which comprises administering by inhalation a pharmaceutically safe and effective amount of an aerosolized vesicant anti-cancer agent; wherein said vesicant anti-cancer agent is unencapsulated.

129. A method according to Claim 128 wherein said anti-cancer agent is selected from the group consisting of anthracyclines, alkylating agents, vinca alkaloids, and taxanes.

130. A method according to Claim 128 wherein said anthracycline anti-cancer agent is selected from the group consisting of doxorubicin, epirubicin, daunorubicin, cyanomorpylinyl-doxorubicin and idarubicin.

131. A method according to Claim 129 wherein said alkylating agent anti-cancer agent is selected from the group consisting of mechlorethamine, mitomycin-C, dactinomycin, and mithramycin.

132. A method according to Claim 129 wherein said anti-cancer agent is a vinca alkaloid.

133. A method according to Claim 132 wherein said vinca alkaloid anti-cancer agent is selected from the group consisting of vincristine, vinblastine, vinorelbine, and vindesine.

134. A method according to Claim 129 wherein said taxane anti-cancer agent is selected from the group consisting of paclitaxel and docetaxel.

135. A method according to Claim 128 wherein said vesicant anti-cancer agent is administered by inhalation as an aerosolized liquid, powder or gas.

136. A method according to Claim 135 wherein said aerosolized vesicant anticancer agent is administered as an aerosolized liquid.

137. A method according to Claim 135 wherein said aerosolized anthracycline is administered as an aerosolized powder.

138. A method according to Claim 132 wherein said vinca alkaloid anti-cancer agent is administered at a dosage of from about 0.1 mg/m² body surface area to about 90.0 mg/m² body surface area.

139. A method according to Claim 138 wherein said vinca alkaloid anti-cancer agent is vincristine and wherein said agent is administered at a dosage of about 1.4 mg/m² body surface area.

140. A method according to Claim 138 wherein said vinca alkaloid anti-cancer agent is vinblastine and wherein said agent is administered at a dosage of about 6.0 mg/m² body surface area.

141. A method according to Claim 138 wherein said vinca alkaloid anti-cancer agent is vinorelbine and wherein said agent is administered at a dosage of about 30.0 mg/m² body surface area.

142. A method according to Claim 138 wherein said vinca alkaloid anti-cancer agent is vindesine wherein said agent is administered at a dosage of about 3.0 mg/m² body surface areas.

143. A method according to Claim 129 wherein said taxane anti-cancer agent is administered at a dosage of from about 10.0 mg/m2 body surface area to about 400.0 mg/m² body surface area.

144. A method according to Claim 143 wherein said taxane is administered at a dosage of from about 20.0 mg/m^2 body surface area to about 75.0 mg/m^2 body surface area.

145. A method according to Claim 129 wherein said anthracycline anti-cancer agent is administered at a dosage of from about 3 mg/m^2 body surface area to about 130 mg/m^2 body surface area.

146. A method according to Claim 128 wherein the particle size of said aerosol is from about 0.1 μm to about 10.0 μm.

147. A method according to Claim 146 wherein the particle size of said aerosol is from about 1.0 μm to about 5.0 μm.

148. A method according to Claim 147 wherein the particle size of said aerosol is from about 2.0 μm to about 2.5 μm.

149. A method according to Claim 128 wherein one or more non-vesicant anti-cancer agents are administered by inhalation at the same time as the vesicant anticancer agent.

150. A method according to Claim 135 wherein said means for aerosolization is selected from the group consisting of metered dose inhalers, nebulizers, and dry powder inhalers.

REMARKS

This application is a continuation of US Serial No. 09/000,775 filed December 30, 1997.

Pursuant to Section 714.09 of the *Manual of Patent Examining Procedure* (MPEP), Applicants herewith submit an amendment preliminary to an action by the Office.

By this amendment, all previously pending claims have been cancelled. New Claims 128 – 150 have been added. The new claims do not introduce new matter and the present invention is fully supported and disclosed by the specification and claims as originally filed.

Examiner's attention is directed to the following specific text of the specification as examples of such support and disclosure.

p. 6, lines 25-32
p.7, lines 1 – 10
p. 10, lines 1-28
p.11, lines 26-32
p. 12, lines 1-30
p. 17, Table 1
p. 35, lines 11-32
p.36, lines 1-8
p. 38, lines 9-24
p.64, Table 14

It is believed that the above-identified application, having Claims 128 – 150 pending, is now in condition for allowance.

Respectfully submitted,

Dated: Feb. 4, 2002

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